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7590 12/06/2004	70/458 EXAMINER	9217
	EXAMINER	
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125 PINELAWN ROAD	1617	KNOMBEK

DATE MAILED: 12/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary		Application No.	Applicant(s)			
		09/838,649	CIOCA ET AL.			
		Examiner	Art Unit			
		Shobha Kantamneni	1617			
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply						
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).						
Status						
1)	Responsive to communication(s) filed on					
2a) <u></u> ☐	a) This action is FINAL . 2b) This action is non-final.					
3)□	3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.					
Disposition of Claims						
4)🖂	4) Claim(s) 1-22 is/are pending in the application.					
	4a) Of the above claim(s) <u>6-8, 13-18, and 21</u> is/are withdrawn from consideration. 5) Claim(s) is/are allowed. 6) Claim(s) <u>1-5,9-12,19,20 and 22</u> is/are rejected.					
5)						
6)⊠						
7)	7) Claim(s) is/are objected to.					
8)[Claim(s) are subject to restriction and/or	election requirement.				
Applicati	on Papers					
9)	The specification is objected to by the Examine	۲.				
10)☐ The drawing(s) filed on is/are: a)☐ accepted or b)☐ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).						
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.						
Priority u	ınder 35 U.S.C. § 119					
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) ☐ All b) ☐ Some * c) ☐ None of:						
1. Certified copies of the priority documents have been received.						
2. Certified copies of the priority documents have been received in Application No						
3. Copies of the certified copies of the priority documents have been received in this National Stage						
	application from the International Bureau	(PCT Rule 17.2(a)).	-			
* See the attached detailed Office action for a list of the certified copies not received.						
Attachment(s)						
1) 🛛 Notic	e of References Cited (PTO-892)	4) Interview Summary	(PTO-413)			
2) 🔲 Notic	e of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ite			
Inforr الـــا (٥) Pape	nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) r No(s)/Mail Date	5) Notice of Informal Pa	atent Application (PTO-152)			

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DETAILED ACTION

Claims 1-22 are pending. Claims 6-8, 13-18, and 21 are withdrawn from consideration, as they are directed to non-elected subject matter. In view of Applicants amendments and response of 7/21/04, the rejections made in the previous office action are withdrawn. The following new rejections are made.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-5, 9-12, 19-20 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cioca et al. (6,451,328) in view of Beerse et al. (6,217,887).

The instant invention is directed to structured water comprising a cluster structure, wherein at least two antimicrobial agents are within the cluster structure, and compositions and methods thereof.

Cioca et al. teach a cosmetic or pharmaceutical composition comprising structured water having at least one biologically active agent, an antioxidant integrated within at least one cluster structure. The structured water comprises a combination of I and S water, wherein I water is characterized by a conductivity of about 500-3500, and a pH of about 2.0-4.0; and S water is characterized by a conductivity of about 600-2500, and a pH of about 10.0-12.0. See column 10,

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lines 8-15. Cioca teaches that the antioxidant is integrated in a cluster structure of structured water by feeding a solution of unstructured feed water containing the antioxidant through a device for producing structured water i.e the process used is same as instant invention. See column 3, lines 3-10, Example I, column 7. Examples of suitable antioxidants include, ginkgo biboba, beta carotene, green tea, ascorbic acid and derivatives thereof, carnosic acid, BHT and BHA. See column 5, lines 49-53. Cioca discloses a method of reducing free radicals from the skin and the skin surface by topically applying to the skin the compositions of the structured water. See column 3, lines 15-20. Cioca teaches that the compositions of structured water having the antioxidant in its cluster structure can be used in skin care products, such as cleansers, toners, moisturizers and in makeup products such as lipsticks and glosses, foundations etc. See column 6, lines 30-35. Cioca further teaches that the structured water can contain within its cluster structure, moisturizing actives, agents used to treat age spots, keratoses, as well as analgesics, anesthetics, anticne agents, antibacterials, antiyeast etc. See column 6, lines 59-67. The reference lacks a teaching of silver ion as biologically active agent (antimicrobials) integrated within cluster structure.

Beerse et al. teach leave-on antimicrobial compositions which provide improved immediate germ reduction. Silver is taught as an active antimicrobial agent. See Col. 7, lines 54-67.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach silver (an antimicrobial) of Beerse et al. as biologically active agent of Cioca et al. and integrate within the cluster structure

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of structured water because 1) Cioca teaches that the activity of biologically active agents can be enhanced when combined with structured water 2) silver is a biologically active agent; thus, one of skill in the art would be motivated to combine the silver and structured water because of the expectation of achieving a topical cosmetic composition that is potent toward bacteria.

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cioca et al. (6,451,328) in view of Beerse et al. (6,217,887) as applied to claims 1-2, 4-5, 9-12, 19-20 and 22, and further in view of Stroud et al. (6,231,837).

Cioca et al. and Beerse et al. references are as discussed above.

Cioca lacks a teaching of potassium sorbate as biologically active agent (antimicrobial) integrated within cluster structure.

Stroud et al. teach cosmetic compositions. Potassium sorbate is disclosed as an antibacterial agent in cosmetic compositions. See Col. 18, lines 43-53. It would have been obvious to one of ordinary skill in the art at the time the invention was made to teach potassium sorbate (an antimicrobial) of Stroud et al. as biologically active agent of Cioca et al. and integrate within cluster structure of structured water containing silver ion because 1) Cioca et al. teach that the activity of biologically active agents, can be enhanced when integrated within the cluster structure of structured water 2) potassium sorbate is a biologically active agent. Thus, one of ordinary skill in the art would be motivated to combine the potassium sorbate, Silver ion and structured water because of the expectation of achieving a topical cosmetic composition that is potent towards bacteria.

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It is respectfully pointed out that a compound and its properties are inseparable (*In re Papesch*), and since the combination of references teach the cosmetic composition of the instant claims, the cosmetic composition must have the property of preserving the cosmetic.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1, 4, 5, 9, 11-12, 19-20, 22 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-5 of copending Application No. 10/183,819. Although the conflicting claims are not identical, they are not patentably distinct from each other because the '819 copending Application teaches a structured water having at least one biologically active agent, an antioxidant within the cluster structure, while the instant invention claims a structured water having at least two biologically active agents, antimicrobial agents within cluster structure. The

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antimicrobial agent of the instant invention encompasses antioxidant of the '819. It would have been obvious to one of ordinary skill in the art at the time invention was made, to substitute a biologically active agent, an antioxidant of '819' in the structured water composition with another biologically active agent, an antimicrobial of the instant invention. One would have been motivated to use an antimicrobial agent as biologically active agent because, as claimed in '819' such compositions can be used for the treatment of dermatological conditions.

This is a <u>provisional</u> obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant argue's that "that there is no similarity between the antimicrobial agent added to structured water in the prior art and the antimicrobial integrated within the cluster structure of the structured water in the present invention, as amended. The present invention, as amended, is the surprising discovery that an antimicrobial agent can be integrated....." This argument is not persuasive. The Examiner respectfully points out that the antimicrobial agent for example silver added to structured water in the prior art, will result in a product with silver integrated within the cluster structure of structured as discussed in the previous office action.

Applicant argue's that "A product by process claim differs from another product by process claim if the starting materials to be processed are separate and distinct from one another". "In the present specification, the feed water for

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cluster stabilization in the present invention is provided at page 7, lines 16-25. The feed water for cluster stabilization in the present invention has a PH of about 6.0 to 6.4 and a C of about 470 to 520 μ S/cm. This is in contrast with the '855 starting water which is taught in claim 1 of the '855 reference as having a PH of about 7 to 7.5 and 250 to 450 μ S/cm. The addition of active agents to structured water as taught in the '855 reference is different than the integration of antimicrobial agents". This argument is not persuasive as discussed in the previous office action, page 7, and further the examiner respectfully points out that 1) Applicant is arguing that their product is distinguished by means of the starting materials, when the claims are directed to the final product 2) if the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable.

Applicant argue's "In the Manatu Declaration, paragraph 8, it is demonstrated that structured water having antimicrobial agent integrated within the cluster structure of water is substantially different than a mere addition of an antimicrobial agent to structured water". This argument is not persuasive.

Applicant's data does not suggest that their product is different from the '855 reference. The Declaration provides no data showing that adding antimicrobial agents to structured water would not result in these agents being integrated into the structured water.

Conclusion

No claims are allowed.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shobha Kantamneni whose telephone number is 571-272-2930. The examiner can normally be reached on Monday-Friday, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

SHEENI PAONACAMMAN SUPERVISORY PATENT EXAMINER